

REMARKS

I. STATUS OF THE CLAIMS

This Amendment and Response (the "Amendment") is submitted in response to the final Office Action dated November 19, 2007 (the "Office Action"). By this Amendment, as outlined above, Applicants amend claims 111-138. Following entry of this Amendment, claims 111-170 remain pending in the application. Claims 111-138 are in independent form.

More specifically, claims 111-138 have been amended to clarify that the biostable, non-thrombogenic polymeric material of the topcoat is different from the hydrophobic elastomeric material of the undercoat. All amendments are fully supported by the originally-filed specification and/or drawings of the present application. For instance, the amendments are supported by the specification at, *inter alia*, page 7, lines 6-13, page 15, lines 29 to page 18, line 6, and page 20, line 6 to page 21, line 27. It is believed that no new matter has been added. The claim amendments made herein do not represent acquiescence in the Examiner's rejections, but rather are made only to expedite prosecution of the present application and/or maintain consistency in claim language. Applicants expressly reserve the right to pursue the subject matter of any previously presented claims in one or more continuation applications.

II. THE REJECTIONS UNDER 35 U.S.C. § 103(a)

In the Office Action, claims 111-113, 120, 121, 124, 125, 129, 130, 136, 137, 139-143, 150, 151, 154, 155, 159, 160, 166, 167, 169 and 170 are rejected under 35 U.S.C. § 103(a) ("Section 103(a)") as allegedly being unpatentable over U.S. Patent No. 5,464,650 to Berg *et al.* (hereinafter "Berg"). In addition, claims 114-119, 122, 123, 126-128, 131-135, 138, 144-149, 152, 153, 156-158, 161-165 and 168 are rejected under Section 103(a) as allegedly being unpatentable over Berg in view of U.S. Patent No. 5,288,711 to Mitchell *et al.* (hereinafter "Mitchell"). The rejections are traversed for at least the following reasons.

A. The Legal Standard

A finding of obviousness requires that "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a).

In its recent decision addressing the issue of obviousness, *KSR International Co. v.*

Teleflex Inc., 127 S. Ct. 1727 (2007), the Supreme Court stated that the following factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, (1966) still control an obviousness inquiry: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *KSR*, 127 S. Ct. at 1734 (quoting *Graham*, 383 U.S. at 17-18).

The Supreme Court rejected a rigid application of the “teaching, suggestion, or motivation” test previously applied by the Court of Appeals for the Federal Circuit. *KSR*, 127 S. Ct. at 1739. The Supreme Court, however, affirmed that it is “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 127 S. Ct. at 1741. Thus, consistent with the principles enunciated in *KSR*, a *prima facie* case of obviousness can be established by showing a suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference *and* to carry out the modification with a reasonable expectation of success, viewed in light of the prior art. The suggestion and the reasonable expectation of success must both be found in the prior art and must *not* be based on the applicant’s disclosure. *In re Dow Chemical Co.*, 837 F.2d 469 (Fed. Cir. 1988).

Accordingly, when an obviousness rejection is based on a combination of elements individually found in the prior art, the M.P.E.P. specifies that after resolution of the *Graham* factual inquiries, Office personnel must articulate all of the following to support a conclusion of obviousness:

(1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely performs the same function as it does separately;

(3) a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and

(4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

M.P.E.P. § 2143(A) (citing *KSR*, 550 U.S. at ____; *Sakraida v. AG Pro, Inc.*, 425 U.S. 273, 282 (1976); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63 (1969); *Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 152, (1950). Accordingly, each claim element must be found in the prior art.

B. The Claims Are Patentable Over Berg

Claims 111-113, 120-121, 124-125, 129-130, 136-137, 139-143, 150-151, 154-155, 159-160, 166-167, and 169-170 are rejected under Section 103(a), as allegedly being unpatentable over Berg. These claims are directed to stents having a coating, wherein the coating comprises, *inter alia*, an undercoat comprising a hydrophobic elastomeric material or an ethylene vinyl acetate copolymer material incorporating an amount of a biologically active material, and a topcoat comprising a biostable polymeric material, which is different from the hydrophobic elastomeric material or ethylene vinyl acetate copolymer material, and which is free of an elutable material when applied to the undercoat. Applicants respectfully submit that Berg fails to teach or suggest a stent having a coating comprising such an undercoat and a topcoat.

In the Office Action, the Examiner acknowledges that Berg fails to teach a coating having a topcoat free of an elutable material. (Office Action at page 3.) However, the Examiner alleges that Berg's disclosure of a therapeutic substance to polymer ratio of 1:100 suggests a topcoat which is "substantially free" of an elutable material. (*Id.* at page 5.) According to the Examiner, "substantially free" is close enough to "free" that a person having ordinary skill in the art would expect the "them to have the same properties." (*Id.* at page 3.) Furthermore, the Examiner contends that the claims do not require a different polymer in the undercoat and the topcoat. (*Id.* at page 6.) For the following reasons, Applicants respectfully disagree.

First, as discussed in the Response dated October 30, 2007, Berg's mere disclosure of a drug-to-polymer ratio of 1:100 does not disclose or suggest a coating configuration in which a topcoat is substantially free of a therapeutic agent, i.e. an elutable material, while an undercoat includes a higher drug-to-polymer ratio. In particular, Berg does not teach or

suggest that the 1:100 ratio should be used in an outer layer of its coating configuration while an inner layer of the coating configuration has a higher ratio of drug (or elutable material)-to-polymer. Moreover, in contrast to the coating of the claims, Berg discloses coating configurations having a higher ratio of drug (or elutable material)-to-polymer in the outer layers than in the inner layers of the coating configuration (2:64-68). However, Berg is silent as a stent having the opposite coating configuration, *i.e.*, a stent having a higher drug (or elutable material)-to-polymer ratio in the inner layer than in the outer layers. Therefore, Berg does not teach or suggest a coating having an outer layer or topcoat that is substantially free of an elutable material let alone one that is free of an elutable material.

In addition, Applicant has amended claims 111-138 to clarify that the biostable polymeric material of the topcoat is different from the hydrophobic elastomeric material or ethylene vinyl acetate copolymer material. In particular, Berg does not disclose a coating having an inner coating layer comprising a first polymer and an outer coating layer comprising a second polymer that is different from the first polymer. In fact, the stents in Berg's working examples were all prepared using a uniform coating composition. None of the stents prepared in Berg's working examples have a plurality of layers having different polymers. Therefore, for this additional reason claims 111-113, 120-121, 124-125, 129-130, 136-137, 139-143, 150-151, 154-155, 159-160, 166-167, and 169-170 are patentable over Berg.

C. The Claims Are Patentable Over Berg in view of Mitchell

Claims 114-119, 122-123, 126-128, 131-135, 138, 144-149, 152-153, 156-158, 161-165 and 168 are rejected under Section 103(a), as allegedly being unpatentable over Berg in view of Mitchell. The Examiner acknowledges that Berg fails to disclose a coating comprising an antibiotic, but relies on Mitchell for the disclosure of a stent comprising an antibiotic to inhibit proliferation of vascular smooth muscle cells. (Office Action at page 4.) The Examiner contends that "[i]t would have been obvious to one of ordinary skill in the art to combine the teaching of a stent comprising an antibiotic as taught by Mitchell et al., to a coated vascular stent as per Berg et al." (*Id.*) For the following reasons, Applicants respectfully disagree.

As discussed above, Berg fails to disclose or suggest a stent having a topcoat that is free of an elutable material. Also, Berg fails to teach or suggest a stent having a coating

having an inner coating layer comprising a first polymer and an outer coating layer comprising a second polymer that is different from the first polymer. Mitchell fails to remedy these deficiencies. In fact, Mitchell never teaches or suggests a polymer coating being disposed on a stent, much less teach or suggest a stent having more than one coating (*i.e.*, an undercoat and a topcoat) having the particular polymer combination recited in the claims. Since the combination of Berg and Mitchell fails to teach or suggest each and every element of the claimed stents, Applicants respectfully submit that the claims are patentable over Berg and Mitchell.

For at least the foregoing reasons, it is believed that independent claims 111-138 are patentable over Berg and Mitchell, either taken alone or in combination. Further, claims 139-168, which depend from claims 111-138, respectively, and claims 169 and 170, which depend from any one of claims 141-168, are also believed to be allowable. Accordingly, Applicants respectfully request that the rejections be withdrawn.

CONCLUSION

In view of the above remarks, Applicants respectfully request that the Examiner reconsider pending claims 111-170 with a view towards allowance.

The Examiner is invited to call the undersigned attorney at (212) 326-3939 if a telephone call could help resolve any remaining issues.

Should any fees be required, please charge such fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: March 17, 2008

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